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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,392	07/19/2000	Andrey A. Boukharov	04983.0130.NPUS01/38-21(5	2901

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/23/2006

42

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/620,392

Applicant(s)

BOUKHAROV ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***RCE***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/3/05 has been entered.

2. It is noted that claims 1-4, 6-9 and 16-21 are currently pending, among which claims 1-4, 6-9 and 16-20 are not amended as compared to the claims 1-4, 6-9 and 16-20 under appeal to the Board of Patent Appeals and Interferences and for which a decision by the Board -- affirmation - - was made. Claim 21 is newly added. All claims are under consideration.

***Specification***

3. The specification is objected to because of the following:

Trademarks are used in this application, such as GENBANK<sup>TM</sup> on page 3. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 3 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01. This objection is reiterated from the previous Office action mailed 2/28/02. While amendments were made in the response filed 6/3/02 to delete the portion "<http://www>" from these browser-executable codes, some of the codes after the amendment are still browser-executable, e.g. "ncbi.nlm.nih.gov/web/genbank/index.html" on page 3. Further, there are still other hyperlink and/or other form or browser-executable codes, such as those on pages 99-100. Applicants are requested to review the entire specification, which encompasses at least 55580 pages (the Abstract is on page 55580), to delete any embedded hyperlink and/or other form or browser-executable code.

Appropriate correction is required.

***Claim Rejections-35 USC § 101/§ 112***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

5. Claims 1-4, 6-9, and 16-21 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is reiterated from the previous Office action mailed 2/28/02. It is noted that the rejection has been affirmed by the Board of Patent Appeals and Interferences in a decision mailed 7/1/04.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds are useful for gene mapping, marker assisted introgression of traits, physical mapping, etc. (pages 9 and 49). All these possible uses are generic to any rice nucleic acid sequences.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein to elucidate biochemical pathways and to screen for biologically active agents. Also, it need further research to discover the markers, such as SNPs. The apparent need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize the markers, etc., does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed nucleic acid such that another non-asserted utility would be well established for the elected nucleic acid compound.

Applicant's arguments filed 10/3/05 have been fully considered but they are not persuasive. It is noted that the arguments are essentially the same as those provided in the appeal

brief filed 11/6/02 (e.g. arguments based on *Brenner v. Mason*; *Juicy Whip, Inc. v. Orange Bang, Inc.*; *In re Brana*; and *Fujikawa v. Wattanasin*, see brief, pages 3-5), which had been fully responded to in the Examiner Answer mailed 2/6/03. The rejection was subsequently affirmed by the Board of Patent Appeals and Interferences in a decision mailed 7/1/04 (Paper No. 35). For response to these arguments, see "(11) Response to Arguments" on pages 6-18 of the examiner answer mailed 2/6/03.

However, it is noted that in the response filed 10/3/05, applicants also based their arguments on a recent court decision in *In re Fisher*, -- F.3d --, 2005 WL 2139421 (Fed. Cir, September 7, 2005). Applicants argue that "the court indicated that the specification disclose 'that an invention is useful to the public as disclosed in its current form,' " that "the court further noted that the specification 'also show that that claimed invention can be used to provide a well-defined and particular benefit,' " and that in the instant application "applicants have provided nucleic acid sequences which are shown in the specification to correlate to known genes. Such a correlation is sufficient to satisfy the utility standard." See page 7 of the response filed 10/3/05. This is not found persuasive. Firstly, the fact pattern that is disclosed in the Fisher case is different from that which is disclosed and claimed in the instant application because an isolated nucleic acid comprising the sequence of SEQ ID NO:1 is specifically disclosed and claimed in this application, but is not disclosed and claimed in Fisher's case. Secondly, the court in the Fisher case explicitly approves the Office's Utility Examination Guidelines, which was based upon in the utility rejection set forth above, by stating that the standards in the guideline "comport with this court's interpretation of the utility requirement of §101." *In re Fisher*, 76 USPQ2d 1225, 1230 (CAFC 2005). Thirdly, in *In re Fisher*, the court does not indicate the specification (i.e. the specification at issue in *In re Fisher*) discloses an invention that is useful to the public as disclosed in its current form and shows that the claimed invention can be used to provide a well-defined and particular benefit. The court, following an analysis of Nelson, 626

F.2d at 856 with regard to substantial utility, does state: "It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). The court also, upon analysis of the specific utility requirement, states: "Thus, in addition to providing a 'substantial' utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). Clearly, the court was stating the requirements for a substantial and specific utility for an invention, not that the specification at issue satisfies these requirements. On the contrary, the court, after analyzing the specific fact pattern of the Fisher case, explicitly states: "Hence, we conclude that Fisher's asserted uses are insufficient to meet the standard for a 'substantial' utility under §101." *In re Fisher*, 76 USPQ2d 1225, 1231 (CAFC 2005).

As to applicants' argument that the nucleic acid sequences in the instant case are shown in the specification to correlate to known genes and thus have utility, etc., it is not found persuasive because while the specification discloses in the table starting on page 104 that the sequence of SEQ ID NO:1 comprises exons and maybe genes, putatively detected by the computer program GenScan, the specification does not show any homology of SEQ ID NO:1 to any known genes with known function/activity. Thus, it would clearly take further research to determine whether SEQ ID NO:1 encodes any protein and the function/activity thereof, if any, as well as any practical utility of the protein.

6. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.



7. Claims 1-4, 6-9 and 16-21 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Since applicants' arguments with regard to the utility rejection are not deemed persuasive for reasons set forth above, the arguments with regard to this enablement rejection are not found persuasive for the same reasons.

It is pointed out that the term "complement" recited in the claims is construed as a sequence that has the same length as and is completely complementary to the sequence of SEQ ID NO:1.

The rejection of claims 1-2 and 17-18 under 35 USC 102(b) was withdrawn in the previous Office action mailed 2/6/03 (The Examiner Answer). The rejection of claims 1-4, 6-9 and 16-20 under 35 USC 112, first paragraph (written description rejection), is hereby withdrawn in view of the decision by the Board of Patent Appeals and Interferences mailed 7/1/04 (Paper No. 35, page 25). Applicants' arguments with regard to these rejections are thus moot.

#### ***Conclusion***

8. No claim is allowed.

Art Unit: 1631

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or

relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.  
Patent Examiner



*John S. Brusca 16 February 2006*  
**JOHN S. BRUSCA, PH.D.**  
**PRIMARY EXAMINER**